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**Genetic Therapy Inc.**

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GROUP 1600

**Fax**

**To:** Examiner Ulrike Winkler, Ph.D.

**From:** Doug Golightly

**OFFICIAL**

**Fax:** 703-308-4242

**Pages:** 4 - Including this one

**Phone:** 703-308-8294

**Date:** 11/04/02

**Re:** Application No. 09/734,836

Dear Examiner Winkler,

Included herewith for filing in App. No. 09/734,836 is a Reply to the Restriction/Election Requirement mailed September 6, 2002.

Respectfully Submitted,

Douglas A. Golightly  
Patent Agent  
Reg. No. 51,244

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Nov 4, 2002  
Date

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Art Unit: 1648

**Luo et al.**

Examiner: Winkler, Ulrike

Application No. 09/734,836

Confirmation No. 4435

Filed: December 12, 2000

Atty. Docket No. 4-30922A/SYS

For: BOVINE IMMUNODEFICIENCY VIRUS (BIV) BASED VECTORS

Commissioner for Patents  
P.O. Box 2327  
Arlington, Virginia 22202

**RESPONSE TO RESTRICTION REQUIREMENT**

Sir:

In response to the Office Action dated September 6, 2002, requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of Group V, represented by claims 27-30, 71-73, 77, and 80. This election is made without prejudice to or disclaimer of the other claims disclosed. This election is made with traverse.

An Extension of Time for one month is hereby requested pursuant to 37 C.F.R. §1.136(a). Please charge Deposit Account No. 19-0134 (In the name of Novartis Pharmaceutical Corporation) in the amount of \$110.00 for payment of the extension fee. The Commissioner is authorized to charge any additional fees under 37 C.F.R. §1.17 that may be required, or credit any overpayment, to Novartis Pharmaceutical Corporation's Deposit Account No. 19-0134.

Applicants respectfully disagree with the Examiner's grouping of claims 26 and 67-70 into Group IV. Applicants submit that the inventions claimed in claim 23 (Group I) and claim 26 (Group IV) amount to subcombination and combination inventions, respectively, and are therefore not patentably distinct.

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MPEP § 806.05(c) sets forth the criteria for distinctness for combinations and subcombinations. In order to establish that combination and subcombination inventions are distinct, two-way distinctness must be demonstrated. The inventions are distinct if it can be shown that a combination as claimed:

- (A) does not require the particulars of the subcombination as claimed for patentability (to show novelty and unobviousness), and
- (B) the subcombination can be shown to have utility either by itself or in other and different relations.

When these factors cannot be shown, such inventions are not distinct.

Here, criterion (A) is not met, because the combination of claim 26 (BIV packaging cell line which comprises an established cell line transformed by the BIV construct of claim 23) does require the particulars of the subcombination of claim 23 (BIV packaging construct) for patentability over the art. Accordingly, Applicants respectfully request that claim 26 be consolidated with claim 23 in Group I.

Applicants further propose that claims 67-70 be moved to Group I along with claim 26. Like claim 26, claims 67-70 are directed to packaging cells comprising certain BIV coding sequences. Therefore, claims 67-70 should be included in Group I as well.


The Examiner has also further restricted Group II to the inventions listed as (H)-(P). Claims 9-17 are restricted between inventions (H)-(O), with only one or two claims per group, whereas claims 40-54 are all grouped together in invention (P), as set forth on page 3 of the Office Action. Applicants propose that at least some of the claims in group (P), represented by claims 40-54, would be better grouped into the inventions (H)-(O). For example, Applicants submit that claim 43 should be grouped in group (H) with claim 9. Both refer to embodiments of the invention wherein the packaging signal is a BIV packaging signal. Claim 47 should be grouped in invention (O) along with claim 17, because both claims refer to embodiments of the invention comprising a cPPT. Claims 50 and 51 should be grouped in invention (M) because these three claims all relate to embodiments of the invention comprising an RNA transport element.

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It is believed that this application is in condition for immediate examination. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call Applicants' undersigned representative.

Respectfully submitted,

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Date: November 4, 2002